

- (b) hyaluronic acid or a pharmaceutically acceptable salt thereof in an amount effective to transport said NSAID into the skin or exposed tissue at the site of the condition, wherein the concentration of the hyaluronic acid or salt thereof is between 1-3% by weight of the composition, and the molecular weight of the hyaluronic acid or salt thereof is between 150,000 and 750,000 Daltons, and
- (c) a pharmaceutical excipient suitable for topical application.

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~~55.~~ The method of Claim ~~54~~ wherein the treatment is applied for a period of weeks.

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~~56.~~ The method of Claim ~~54~~ or ~~55~~ wherein the concentration of the NSAID is between 1-5% by weight of the composition.

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~~57.~~ The method of Claim ~~54~~ or ~~55~~ wherein the NSAID is selected from the group consisting of diclofenac, diclofenac sodium, indomethacin, naproxen, (+/-) tromethamine salt of ketorolac, ibuprofen, piroxicam, acetylsalicylic acid and flunixin and wherein the concentration of the NSAID is between 1%-5% by weight of the composition.

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~~58.~~ The method of Claim ~~54~~ or ~~55~~ wherein the concentration of hyaluronic acid or salt thereof is 2 1/2% by weight of the composition and the concentration of NSAID is 3% by weight of the composition.

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~~59.~~ The method of Claim ~~54~~ or ~~55~~ wherein the hyaluronic acid or salt thereof is sodium hyaluronate and is in the concentration of 2 1/2% by weight of the dosage amount and the NSAID is diclofenac sodium and is in the concentration of 3% by weight of the dosage amount.

60. ~~7~~ A method of treating a mammal for a condition of the skin or exposed tissue selected from the group consisting of basal cell carcinoma and actinic keratosis, which method consists essentially of topically administering to the site of the condition, more than once per day over a period of days sufficient to treat the condition, a non-toxic effective dosage amount of a composition consisting essentially of

(a) a non-steroidal anti-inflammatory drug (NSAID) in an amount sufficient to block prostaglandin synthesis, wherein the concentration of the NSAID between 1-5% by weight of the composition,

(b) hyaluronic acid or a pharmaceutically acceptable salt thereof in an amount effective to transport said NSAID into the skin or exposed tissue at the site of the condition, wherein the concentration of the hyaluronic acid or salt thereof is between 1-3% by weight of the composition, and the molecular weight of the hyaluronic acid or salt thereof is between 150,000 and 750,000 Daltons, and

(c) a pharmaceutical excipient suitable for topical application.

92 cont'd
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61. ~~7~~ The method of Claim ~~60~~ wherein the treatment is applied for a period of weeks.

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62. ~~7~~ ~~8~~ The method of Claim ~~60~~ or ~~61~~ wherein the NSAID is selected for the group consisting of diclofenac, diclofenac sodium, indomethacin, naproxen, (+/-) tromethamine salt of ketorolac, ibuprofen, piroxicam, acetylsalicylic acid and flunixin.

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63. ~~7~~ ~~8~~ The method of Claim ~~60~~ or ~~61~~ wherein the hyaluronic acid or salt thereof is sodium hyaluronate in a concentration of 2 1/2% by weight of the composition and the NSAID is diclofenac sodium and is in the concentration of 3% by weight of the dosage amount.

10 ~~64~~¹¹ A method of treating a mammal for actinic keratosis of the skin or exposed tissue, which method consists essentially of topically administering to the site of the actinic keratosis, more than once per day over a period of days sufficient to treat the actinic keratosis, a non-toxic effective dosage amount of a composition consisting essentially of

(a) a non-steroidal anti-inflammatory drug (NSAID) in an amount sufficient to block prostaglandin synthesis,

(b) hyaluronic acid or a pharmaceutically acceptable salt thereof in an amount effective to transport said NSAID into the skin or exposed tissue at the site of the actinic keratosis, wherein the concentration of the hyaluronic acid or salt thereof is between 1-3% by weight of the composition, and the molecular weight of the hyaluronic acid or salt thereof is between 150,000 and 750,000 Daltons, and

(c) a pharmaceutical excipient suitable for topical application.

12
~~65~~¹² The method of Claim ~~64~~ wherein the treatment is applied for a period of weeks.

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~~66~~¹² The method of Claim ~~65~~ wherein the percent of the NSAID in the composition is between 1-5% by weight of the composition.

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~~67~~^{11 12 13} The method of Claim ~~64~~, ~~65~~, or ~~66~~ wherein the NSAID is selected from the group consisting of diclofenac, diclofenac sodium, indomethacin, naproxen, (+/-) tromethamine salt of ketorolac, ibuprofen, piroxicam, acetylsalicylic acid and flunixin.

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~~68~~¹⁴ The method of Claim ~~64~~ wherein the hyaluronic acid or salt thereof is sodium hyaluronate having a molecular weight between 150,000 daltons and 750,000 daltons and is in the concentration of 2 1/2% by weight of the

composition and the NSAID is diclofenac sodium and is in the concentration of 3% by weight of the composition.

16/ 15/
69. The method of Claim 68 wherein the pharmaceutical excipient comprises an effective amount of a solubilizer for the diclofenac sodium.

17/ 16/
70. The method of Claim 69 wherein the solubilizer is methoxypolyethylene glycol.

18/ 15/
71. The method of Claim 68 wherein the pharmaceutical excipient comprises sterile water and an effective solubilizing amount of methoxypolyethylene glycol 350 for the diclofenac sodium.

REMARKS

Claims 54 to 71 inclusive remain in the Application. By these amendments no new subject matter has been added. Particularly, please note that the limitation of the concentration of 1% of the hyaluronic acid or pharmaceutically acceptable salt thereof in the composition is found in the Application at page 18, line 22 to page 19, line 2

"...a 1% lotion of hyaluronic acid..."

Applicant respectfully submits that these claims patentably distinguish over the prior art and are fully supported by the Disclosure in the Application.

In view thereof, Applicant respectfully submits that the Application is in condition for allowance and same is respectfully requested at the earliest convenience.